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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/797,449

03/10/2004

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1-37213

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42715 7590 02/14/2008
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EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

02/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/797,449	Applicant(s) OSBORNE ET AL.	
	Examiner CHERYL MILLER	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 16-28 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 and 8 is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-11, and 13-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-11 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to the McGuckin (US 6,676,698 B2) rejection have been found persuasive. These rejections have been withdrawn.

The applicant has argued that Snyders (US 2002/0123802 A1) does not disclose the frame and valve cooperatively forming the opening 212. The examiner disagrees. Referring to figure 8, post 310 is disclosed to be integral and part of the frame. 310 is shown in dashed lines to extend to the valve material 222. Opening 212 is formed and bordered by both a portion of the frame (310) and the valve (222). This is shown clearly in figure 8. Further in P0058, Snyders discloses the opening 212 to extend through "*at least one* of the frame 220 and valve element 222". Thus "at least one" encompasses one or more and Snyders supports the opening extending through both the frame and valve.

The applicant has argued that Shaolian et al. (US 2003/0055492 A1) does not disclose an opening of a fixed size. The examiner disagrees. The applicant has claimed the opening defined during flow in the second opposite direction. During fluid flow in the second direction, Shaolian's opening is of a fixed size. It only changes when the direction of flow changes (such as flow in the first direction). If applicant were to claim the fixed size during both directions of flow or in both the leaflets first and second positions, this would overcome the Shaolian rejection.

The applicant has argued that Baykut (US 4,787,901) does not disclose fluid flow in a second opposite direction that flows *through* the device. The examiner disagrees. The device comprises both the frame (3) and the valve (2). When fluid flows in the opposite direction (seen by arrow in fig.10), the fluid travels through the valve portion of the device, exiting through arteries (10 and 11; col.5, lines 65-68).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Snyders (US 2002/0123802 A1, cited previously). Snyders discloses an implantable medical device (see figs.8-15) comprising an expandable support frame (220) and at least one leaflet (257 of valve 222) attached to the frame and at least partially defining a valve orifice (near 240, see fig.8, 9) that regulates flow, the leaflet made of a bioremodelable material (P0043) and movable between two positions (fig.8, 9), wherein the frame (220) and leaflet (257 of 222) cooperatively define an opening (212) that permits a controlled amount of fluid to flow in a second direction (P0058), the opening (212) spaced axially from orifice (near 240).

Claims 1-3 and 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Shaolian et al. (US 2003/0055492 A1, cited previously). See figures 1-4. Shaolian discloses an

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implantable medical device comprising an expandable support frame (44) and at least one leaflet (42, seen clearly in fig.2a) at least partially defining a valve orifice (seen at top right of 42 in fig.3 in the open position) being movable between two positions (closed in fig.2, open in fig.3), a first edge attached to the frame (attached at 68, 70 to 60 and 62) and second edge unattached (all other portions of periphery are unattached, for instance bottom edge at 75 seen in fig.2a), wherein a portion of the second edge and frame (44) define an opening (bottom left of 42 in fig.3; disclosed to minimize retrograde flow, therefore, some flow exists; P0064), the opening (at bottom of leaflet) spaced axially from orifice (at top of leaflet, see fig.2a, 3) the opening having a fixed shape (at least while flow exists in the second opposite direction). Shaolian discloses a self-expanding frame (P0051). Shaolian has shown the opening (bottom of leaflet) to open less than 25 percent about (fig.3).

Claims 1, 2, 4, 5, 9, 10, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Baykut (US 4,787,901, cited previously). Baykut discloses a medical device (see figs.1,2, 9, 10 for example) comprising an expandable frame (3) and at least one leaflet (2) defining a valve orifice (top of frame3, where 7 moves to open and close), the leaflet having first and second edges and is movable, the first edge attached to the frame (at 6; common wall 7, see fig.1) and second edge being free (bottom of 2, seen clearly in fig.9, 10; all of leaflet not sharing a common wall 7), wherein a portion of the frame (3) and second edge (bottom edge of 2 and perimeter of 2 not sharing wall 7) form an opening (seen in figs.9, 10 below stitching 15 of 2 to vessel), the opening (bottom of 2) is axially spaced from orifice (top of 3), the opening having a fixed shape (at least fixed during flow in the second direction). Baykut's frame (3) is self-

expandable (flexible materials capable of being compressed/folded and expanded), the leaflet (2) is bioremodelable (biological materials, col.5, lines 30-40).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaolian et al. (US 2003/0055492 A1, cited previously). Shaolian discloses a valve leaflet made of PTFE (P0059) and does not disclose the leaflets to be made of bioremodelable material such as submucosa. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the leaflets formed of such bioremodelable material since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin* 125 USPQ 416.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Snyders (US 2002/0123802 A1, cited previously). Snyders discloses a valve leaflet made of biological tissues (P0054), however does not disclose specifically small intestinal submucosa. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the leaflets formed of submucosa since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin* 125 USPQ 416.

Allowable Subject Matter

Claims 7 and 8 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738